

NEUROSURGERY

BRAIN, SPINAL, STEREOTACTIC AND MICRONEUROLOGICAL SURGERY

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Diplomate American Board of Neurological Surgery

Fellow Royal College of Surgeons (Canada)

Diplomate American Board of Neurological Surgery

Fellow American College of Surgeons

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Document Management Branch (HFLA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Re: Docket No. 97N-484s

To whom it may concern:

I received a note from Medtronic Sofamore Danek Company (spinal hardware company) regarding the above issue. It sounds, from the letter I received, that the FDA would regulate some types of allograft materials. I am not certain about what exactly is in this legislation, but I have been using allograft bone for fusion purposes for years in the spine (primarily cervical spine) with excellent results. If this involves threaded bone dowels for the purposes of lumbar interbody fusion, then I feel that clinical trials should be done.

Best Regards.

Sincerely,



Scott Lederhaus, M.D.

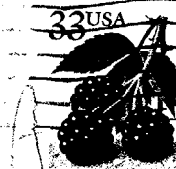
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